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Orodispersible Tablets: An approach for drug delivery in buccal cavity

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ABSTRACT: The objective of the dosage form for delivery of drug at specific site to get desired therapeutic effect of drug. The ideality of the delivery system to achieve the maximum therapeutic effect and minimum adverse effect. Oral delivery is the most convenient, economical and safest route for drug delivery. Still it possess a demerit of difficulty in swallowing of tablets and capsules. The Oral Dispersible Tablets (ODTs) is a novel approach to overcome the above mentioned problem. The ODTs is rapidly disintegrate and dissolved in saliva. The oral cavity is highly vascularized and internally lined with epithelial and mucous membrane which favors rapid absorption of drug, thus ODTs provide quick onset of action. The ODTs possess other merits of ease the administration especially in case of pediatrics and geriatrics, low cost production, less use of water and less drug loss. The patients suffering from dysphasia, motion sickness, repeated emesis and mental disorders preferably use ODTs because they cannot swallow large quantity of water. The ODTs can be design by employing several techniques such are Melt Granulation, Effervescent Method, Cotton candy process, Direct Compression, Tablet Molding, Sublimation, Phase Transition, Freeze drying and mass extrusion. The several marketed ODTs formulations along with numerous scientific advancements has been focused in this review study.

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INTRODUCTIONS:

Current Pharmaceutical Dosage forms include Novel Drug Delivery Systems (NDDS) which is targeted to enhance safety and efficacy of drug molecule to improve the treatment compliances and quality of life of patients. The novel approach is Mouth Dissolving Tablet (MDT) which disintegrates instantly when placed on tongue, releasing the drug that dissolves or disperses in the saliva. Difficulty in swallowing (Dysphagia) is a common problem of all age groups, especially elderly

and pediatrics, because of physiological changes associated with these groups of patients. The saliva containing dissolved or dispersed medicament is then swallowed and the drug is absorbed in the normal way. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach and it may produce rapid onset of action, with bioavailability of drug significantly greater than those observed from conventional tablet dosage form [1,2].

TABLETS:

Solid medicaments may be administered orally as powders, pills, cachets, capsules or tablets. These dosage forms contain a quantity of drug which is given as a single unit and they are known collectively as solid unit dosage forms, even in the case of sustained action preparations which, technically, contain the equivalent of several normal doses of drug. Tablets and capsules, on the other hand, currently account for well over two third of the total number and cost of medicines produced all over the world [1,2].

Definition:

Tablet is defined as a compressed solid dosage form, flat or biconvex dishes, containing medicaments with or without excipients. It is the most popular dosage form and 70 % of the total medicines are dispensed in the form of Tablet [1].

Advantages:

They are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability. Cost is lowest of all oral dosage form. Lighter and compact. Easiest and cheapest to package and strip. Easy to swallowing with least tendency for hang-up. Sustained release product is possible by enteric coating. Objectionable odour and bitter taste can be masked by coating technique. Suitable for large scale production. Greatest chemical and microbial stability over all oral dosage form. Product identification is easy and rapid requiring no additional steps when employing an embossed and/or monogrammed punch face [2,3].

Disadvantages:

Difficult to swallow in case of children and unconscious patients. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character. Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will

still provide adequate or full drug bioavailability. Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost [2,3].

Types of tablets:

Tablets ingested orally: Compressed tablet (Paracetamol tablet), Multiple compressed tablet, Repeat action tablet, Delayed release tablet (Enteric coated Bisacodyl tablet), Sugar coated tablet (Multivitamin tablet), Film coated tablet (Metronidazole tablet) and Chewable tablet (Antacid tablet); Tablets used in oral cavity: Buccal tablet (Vitamin-c tablet), Sublingual tablet (Vicks Menthol tablet), Troches or lozenges and Dental cone; Tablets administered by other route: Implantation tablet and Vaginal tablet (Clotrimazole tablet); Tablets used to prepare solution: Effervescent tablet (Dispirin tablet), Dispensing tablet (Digiplex), Hypodermic tablet and Tablet triturates (Enzyme tablet) [3,4].

Tablet ingredients:

In addition to active ingredients, tablet contains a number of inert materials known as additives or excipients. Different excipients are Diluent, Binder and adhesive, Disintegrants, Lubricants and glidants, Colouring agents, Flavoring agents and Sweetening agents [6].

Manufacturing of tablets [6-8]:

Direct compression:

The direct compression method for manufacturing the tablets consists of various steps (Fig 1) that are Raw material, Weighing, Screening, Mixing and Compression. Direct compression consists of compressing tablets directly from powdered materials without modifying physical nature of materials. This method is applicable for crystalline chemicals having good compressible characteristic and flow properties.

Dry granulation:

The dry granulation method for manufacturing the tablets consists of various steps (Fig 1) that are Raw material, weighing, Screening, Mixing, Slugging, Milling, Screening, Mixing and Compression. When tablet ingredients are sensitive to moisture and/or unable to withstand elevated temperature during drying and when the tablet ingredient have insufficient cohesive properties, slugging may be used to form granules. This method is referred to as dry granulation. This technique is used in preparation of aspirin, aspirin combination,

acetophenetidin, thiamine hydrochloride, ascorbic acid, magnesium hydroxide.

Wet granulation:

The wet granulation method for manufacturing the tablets consists of various steps (Fig 1) that are Raw materials, Weighing, Screening, Wet massing, Sieving/Milling, Drying, Screening, Mixing and Compression. The most widely used and most general method of tablet preparation is the wet granulation method. The active ingredient, diluent and disintegrates are mixed or blended well.

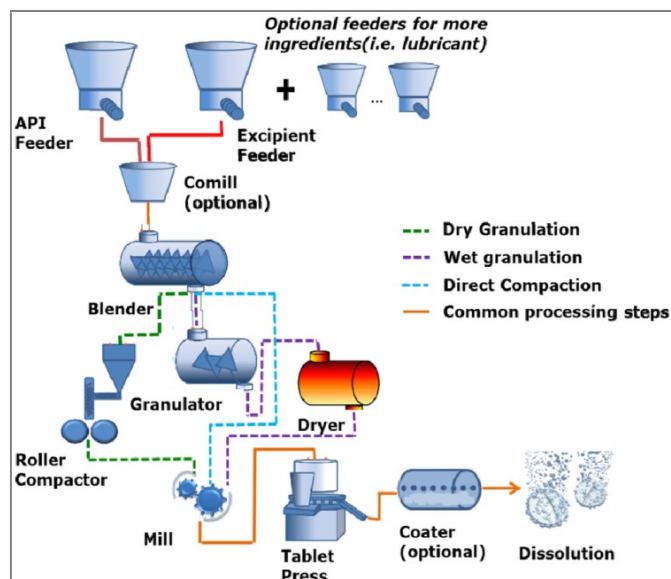


Fig 1. Schematic representation of granulation techniques.

ANATOMY OF ORAL CAVITY:

The oral cavity (Fig 2) lies anterior to the oropharynx and is separated from it by the circumvallate papillae, soft palate and anterior tonsillar pillars, which make up its posterior boundary.

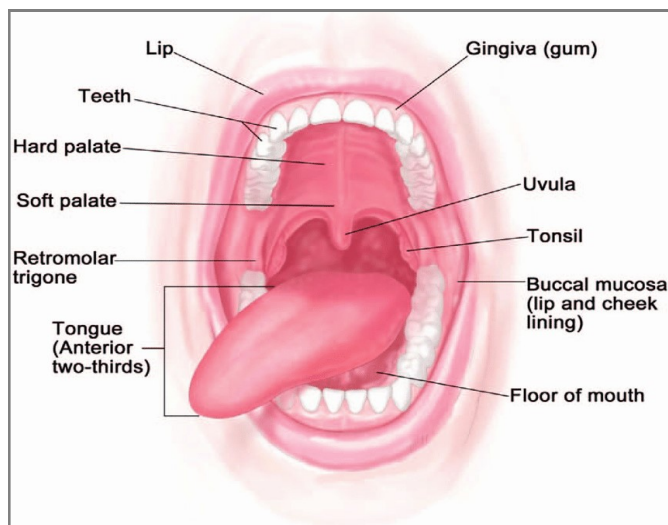


Fig 2. Anatomy of human oral cavity.

The oral cavity is bounded superiorly by the hard palate, laterally by the cheek, and inferiorly by the mylohyoid muscle. In addition to the mucosal area of the oral cavity (the dominant structure of which is the oral tongue), the mylohyoid muscle cleaves the lower oral cavity into the sublingual and submandibular spaces. The sublingual space is frequently invaded by tumors of the floor of the mouth. The submandibular space is most commonly involved by inflammatory processes or metastases to level-I lymph nodes [9].

Oral Mucosa:

The oral mucosa (Fig 3) is the mucous membrane lining the inside of the mouth. It comprises stratified squamous epithelium and an underlying connective tissue termed lamina propria. The oral cavity has sometimes been described as a mirror that reflects the health of the individual. The oral mucosa is an attractive delivery site due to its large surface area for absorption (100 to 200 cm²), easy accessibility, limited proteolytic activity and high degree of vascularization [10].

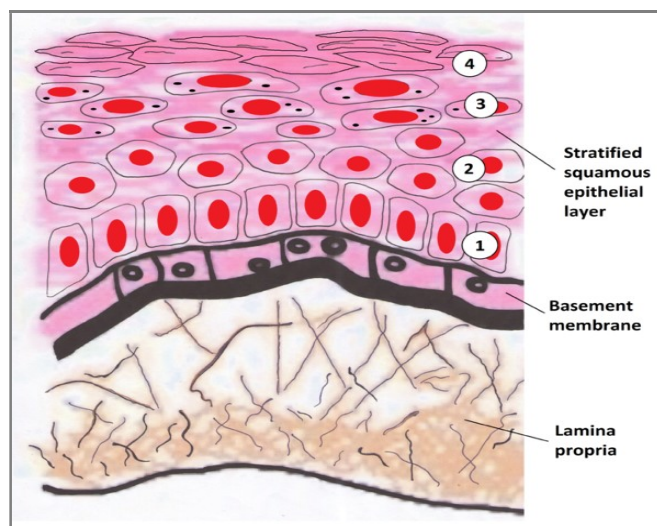


Fig 3. Mucous membrane structure in oral cavity.

Mechanism of drug permeation in oral cavity:

The buccal mucosa and the skin have similar structures with multiple cell layers at different degrees of maturation. The buccal mucosa, however, lacks the intercellular lamellar bilayer structure found in the stratum corneum, and hence is more permeable (Fig 4). An additional factor contributing to the enhanced permeability is the rich blood supply in the oral cavity. The lamina propria, an irregular dense connective tissue, supports the oral epithelium. Though the epithelium is avascular, the lamina propria is endowed with the presence of small capillaries. These vessels drain absorbed drugs along with the blood into three major

veins-lingual, facial, and retro-mandibular, which open directly into the internal jugular vein [11].

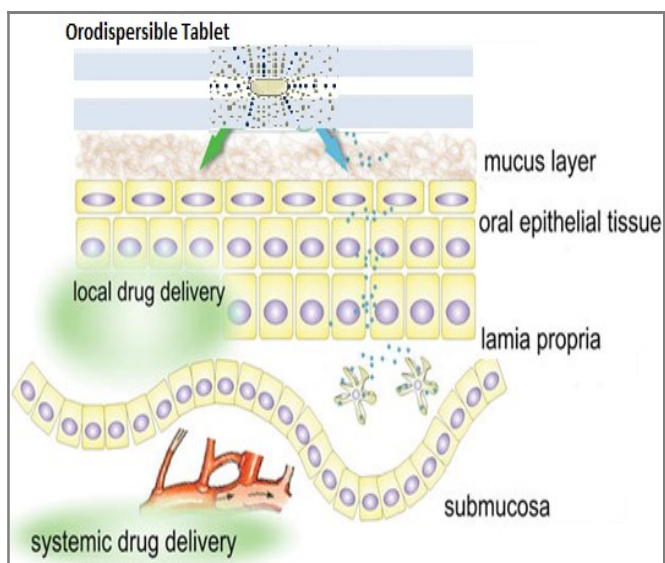


Fig 4. Mechanism of drug release from ODTs.

ORODISPERSIBLE TABLET (ODTs):

For most therapeutic agents used to produce systemic effects, the oral route still represents the preferred way of administration owing to its several advantages and high patient compliance compared to many other routes. Orodispersible tablets are also called as orally disintegrating tablets, mouth-dissolving tablets, rapid dissolving tablets, fast-disintegrating tablets, fast-dissolving tablets.

Definition:

Oro dispersible tablets (ODT) are solid single-unit dosage forms that are placed in the mouth, allowed to disperse/dissolve in the saliva (Fig 5) and then swallowed without the need for water [12].



Fig 5. The dissolve state of orodispersible tablet.

Objectives:

ODTs provide immediate therapy for acute diseases. ODTs achieve sudden therapeutic compliance. ODTs provide faster drug release in to systemic circulation. ODTs enhance bioavailability of drug. ODTs patient compliances for patient suffering from Dysphagia [13].

Advantages:

Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure and patients who refuse to swallow such as pediatric, geriatric and psychiatric patients. ODTs provide rapid drug therapy intervention. ODTs achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx and esophagus as saliva passes down. ODTs are convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water. Good mouth feel property of ODTs helps to change the perception of medication as bitter pill particularly in pediatric patients [14,15].

Disadvantages:

This formulation is Hygroscopic in nature. In ODTs, low amount of drug can be incorporated in each dose. Sometime ODTs possesses mouth feeling effect. ODTs are sometimes highly fragile. ODT requires special packaging for properly stabilization and safety of stable product. Eating and drinking may become restricted while administering the ODTs [14,15].

Ideal characteristics of ODTs:

Orally disintegrating drug delivery system should possess following characteristics: Utilizes cost effective production method, require no water for oral administration, dissolve / disperse/ disintegrate in mouth in a matter of seconds, have a pleasing mouth feel and taste masking, less friable and have sufficient hardness, leave minimal or no residue in mouth after administration and manufacturing using conventional manufacturing method [16].

Challenges in developing ODTs:

Several challenges comes into the play in formulation the ODTs, such are rapid disintegration of tablet, avoid increase in tablet size, have sufficient mechanical strength, minimum or no residue in mouth, protection from moisture, good package design, compatible with taste masking technology and not affected by drug properties [17].

Major excipient used in formulation of ODTs:***Superdisintegrants:***

Now a days the faster disintegrating formulation is increased, hence it is required to formulate disintegrants i.e. Superdisintegrants. This superdisintegrants act by swelling and as result of swelling pressure exerted in the outer direction or radial direction, it causes tablet to burst or the accelerated absorption of water leading to an enormous increase in the volume of granules to promote disintegration. The various types of Superdisintegrants used are Crosspovidone, Microcrystalline cellulose, Sodium starch glycolate, Sodium carboxy methyl cellulose or cross carmellose sodium, Pregelatinized starch, Calcium carboxy methyl cellulose, Modified corn starch, Sodium starch glycolate has good flowability than Cross carmellose sodium^[18-20].

Factors to be considered for selection of superdisintegrants for use are mentioned as follows that are it should produce mouth dissolving when tablet meets saliva in the mouth; it should be compactable as enough to produce less friable tablets; it should able to produce good mouth feel to the patient. Thus, small particle size is preferred to acquire patient compliance and it should have good flow since it improve the flowability of the total blend^[18-20].

Taste masking agents:

These agents are used for masking the bitter taste of drug. Taste masking of bitter or with objectionable tasting drug substances is critical for any orally administered dosage form drugs for ODT. Less commonly, active pharmaceutical ingredients to be incorporated are tasteless and do not require taste masking. Sugar based excipient are used for taste masking and as bulking agents. Examples are Sorbitol, mannitol, xylitol, dextrose and fructose^[18-20].

Binders:

Main role of Binders is to keep the composition of these fast melting tablets together during the compression stage. Binders commonly used are cellulosic polymers (Ethyl cellulose, HPC and HPMC), povidones, PVA, and acrylic polymers. The most commonly acrylic polymers are used are the ammonio methacrylate copolymer (Eudragit RL and RS), polyacrylate^[18-20].

Methodology^[21-24]:***Melt Granulation:***

Melt granulation technique is a process by use of which pharmaceutical powders are efficiently agglomerated by

a meltable binder. The advantage of this technique compared to a conventional granulation technique is that no water or organic solvents are required. Because there is no drying step involved, the process is less time consuming and uses less energy than wet granulation. The technique increases the dissolution rate of poorly water-soluble drugs.

Effervescent Method:

Orodispersible tablets are also prepared by effervescent method by mixing sodium bicarbonate and tartaric acid or citric acid of concentration 12 % (w/w) along with super disintegrants like pregelatinized starch, sodium starch glycolate, crospovidone, and croscarmellose.

Cotton candy process:

In this process Shearform technology is used in the preparation of a matrix known as floss, made from the combination of the recipients either alone or with the drugs. The fibrous nature of the floss is similar to the cotton-candy fibers. The floss is commonly made of saccharides such as sucrose, dextrose, lactose and fructose at temperatures ranging between 180 to 260 °F.

Direct Compression:

It is the simplest and most cost effective tablet manufacturing technique for ODTs as they can be fabricated using conventional tablet manufacturing and packaging machinery and also due to availability of tableting excipients with improved flow, compressibility and disintegration properties, especially tablet disintegrants, effervescent agents and sugar based excipients.

Tablet Molding:

Tablets produced by molding are solid dispersions. Physical form of the drug in the tablets depends whether and to what extent, it dissolves in the molten carrier. The drug can dissolve totally in the molten carrier to produce solid solution.

Sublimation:

The key to rapid disintegration for orodispersible tablets is the presence of a porous structure in the tablet matrix. Hence, to produce porous matrix, volatile ingredients are used that are later subjected to a process of sublimation. Sublimation is a process in which water passes directly from solid state to vapour state without passing through liquid state. This process involves addition of inert volatile substances like urea, urethane, naphthalene, camphor and menthol.

Phase Transition:

The ODTs were produced by compressing powder containing erythritol (melting point: 122 °C) and xylitol (melting point: 93 to 95 °C), and then heating at about 93 °C for 15 min. After heating, the median pore size of the tablets was increased and tablet hardness was also increased. The increase of tablet hardness associated with heating and storage did not depend on the crystal state of the lower melting point sugar alcohol.

Freeze Drying:

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve or disperse rapidly. The active drug constituent is dissolved or dispersed in an aqueous solution of a carrier/polymer. The trays holding the blister packs are transferred through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packages are placed in refrigerated cabinets to continue the freeze-drying process.

Mass-Extrusion:

This technology involves softening the active blend using the solvent mixture of water soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.

Characterization ODTs [25-27]:**Hardness/ Crushing strength:**

It is the force required to break a tablet by compression in the radial direction, it is an important parameter in formulation of ODTs because excessive crushing strength significantly reduces the disintegration time. Instrument used are Monsanto hardness tester and Pfizer hardness testers.

Thickness:

Tablet thickness can be measured by using Vernier calipers. The thickness of tablet is expressed in mm.

Friability:

Friability indicates the ability of a tablet to withstand mechanical shocks while handling. Friability of the tablets were determined using Roche Friabilator and is expressed in percentage. The percentage loss of tablet after friability should be less than 1 %.

Water absorption ratio (WAR):

WAR was measured by keeping a tablet on a piece of tissue paper folded twice in a small culture dish containing 6 ml of phosphate buffer pH 6.8 and water respectively. The time required for water to reach the upper surface of the tablet was the wetting time.

Wetting time:

Piece of tissue paper folded twice was placed in small petridish containing 6 ml of water. A tablet was put on the paper and the time required for complete wetting of tablet was noted.

In vitro disintegration time:

In vitro disintegration time was measured by using 200 ml distilled water in 250 ml beaker at 37± 0.5 °C temperature. Time required for disintegration of the tablets was noted.

Mouth feel:

To know mouth feel of these tablets, selected human volunteers were given placebo tablets and the taste sensation felt was evaluated.

Weight variation:

About 20 tablets were selected randomly and weighted individually to check for weight variation.

Tablet Porosity (ϵ):

The mercury penetration porosimeter can be used to measure the tablet porosity and it can be calculated by using following equation, $\epsilon = 1 - m / (\rho_t V)$ ----- (1)

Where, ρ_t , m and V are true density, weight and volume of the tablet, respectively.

Dissolution test:

The dissolution method for ODTs are practically identical to conventional tablet when ODTs does not utilize taste masking. Commonly the drugs may have dissolution conditions as in USP monograph. The study is carried out in 0.1N HCl, pH 4.5 and pH 6.8 buffers should be used for evaluation of ODTs. USP 2 paddle apparatus is most suitable and common choice for dissolution test of FDT tablets.

MARKETED PRODUCTS:

Various drugs used for several acute diseases are marketed as commercialized product as detail given in Table 1 [28].

PATENTS:

Patented technologies for ODTs are summarized in Table 2 [29].

Table 1. Various marketed product of Oral Dispersible tablets.

Brand name	Active ingredient	Application	Company
Claritin® RediTabs®	Loratadine	Antihistamine	Scherig corporation
Feldene Melt®	Piroxicam	NSAIDs	Pfizer
Maxalt® -MLT®	Rizatriptan benzoate	Migrane	Merck
Zyperxa®	Olazepine	Psychotropic	Eli Lilly
Zofran® ODT	Olandansetron	Antiemetic	Galaxo Smith kline
Zelapar™	Selegiline	Parkinsons disease	ElanAmarinCorp.
Triaminic® Softchews®	Various combination	Pediatric cold cough,Allergy	Novartis consumer Health
TempraQuicksolv®	Acetaminophen	Analgesic	Bristol-Mterssquibb

Table 2. Different patents of Oral Dispersible tablets.

Patented Technology	Technology Based on	Technology developed by Company	Example (Brand name)
Zydis36, 37	Porous matrix	Porous matrix	Olanzapine (ZyprexaZydis)
Quicksolv38	Lyophilization	Germany Janssen Pharmaceutical Inc	Cisapride monohydrate (PropulsidQuicksolv)
Lyoc39	Freeze drying	USA, Pharmalyoc,France	Phloroglucinol Hydrate (SpasfonLyoc)
Flashtab40	Tableting with disintegrants and swelling agents	Ethypharm France	Ibuprofen (NurofenFlashTab)
Orasolv41, 42	Tableting with effervescent disintegrants	Cima Labs, Inc USA	Paracetamol (TempraQuicklets)
Durasolv43	Direct compression	Cima Labs, Inc. USA	Zolmitriptan (Zolmig ZMT)
Wowtab44, 45	Tableting with low and high moldability saccharides	Yamanouchi Pharma Tech., Inc., USA	Famotidine (Gaster D)

FUTURE TREND:

These dosage forms may be suitable for the oral delivery of drugs such as protein and peptide based therapeutics those have limited bioavailability when administered by conventional tablets. These products usually degrade rapidly in the stomach and next generation drugs may be pre dominantly protein or peptide based, tablets may no longer be the dominant format for dosing such moieties. The developments of enhanced oral protein delivery technology by ODTs which may release these drugs in the oral cavity are very promising for the delivery of high molecular weight protein and peptide [30].

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